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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,243	12/27/2001	Karen L. Fearon	377882001800	8533

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	**PAPER NUMBER**
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/033,243	FEARON ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,24 and 26-48* is/are pending in the application.

4a) Of the above claim(s) *5-8 and 27-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,9-21,24,26,47 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 12-11-06 has been entered.

Claims 1-21, 24 and 26-48 are pending. Claims 5-8, 27-46 are withdrawn. Claims 1-4, 9-21, 24, 26 and 47-48 are under examination.

Rejections Withdrawn

The rejection of claims 9-21 and 48 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendments to the claims entered pursuant to the Advisory Action of 10-25-06.

The rejection of claims 9-21 under 35 U.S.C. 112; second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims entered pursuant to the Advisory Action of 10-25-06.

Rejections Maintained

Claims 1-4, 9-21, 24, 26 and 47-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated immunostimulatory oligodeoxynucleic acids consisting of SEQ ID NOs:18, 38 and 59, wherein the immunostimulatory polynucleotide is fully modified phosphorothioate oligodeoxynucleotides and said immunostimulatory oligodeoxynucleic acids increase IFN-gamma or IFN-alpha and compositions comprising such and wherein the immunostimulatory

nucleic acid is optionally complexed with cationic poly(lactic acid, glycolic acid) microspheres, it does not reasonably provide enablement for immunomodulatory nucleic acids, immunostimulatory nucleic acids in general, and biodegradable microcarriers in general, or oligoriboxynucleotides, immunostimulatory sequences liked to cationic poly(lactic acid, glycolic acid) by any means or biodegradable carriers in general is maintained for reasons made of record in the Office Action mailed 8-1-05.

Applicants' arguments have been carefully considered but are still not persuasive for all the reasons made of record. Applicants argue that the examiner focuses on the definition of "ISS" to the exclusion of the other pages of the specification. Applicants again argue the broad teaching of the specification on how to make. This issue is not how to make but the lack of correlation of the genus structure with the breadth of the claimed function. Applicants argue that pages 23-32 details the different substitutions that can be made to generate a limited population of ISS. This is not persuasive, the claims are much broader because they are not limited to the particular variants of SEQ ID NO:62, but encompasses alterations 3' and 5' in the nucleic acid sequence, changes to nucleotides (i.e. sugar modifications etc) that unpredictably affect activity and have not been demonstrated to have any activity. Therefore, unlike Applicants assertion and belief, the claims are not limited to the specific 10-mers described in the specification, but are in fact much broader (see the non-exhaustive list of modifications at page 32). Applicants have not demonstrated the functionality of the modifications encompassed by the claims and the specification such as sugar modifications or other base modification, single stranded, double stranded etc. that function as claimed. Applicants argue that the examiner is wrong in indicating that Applicants have claimed all ISS's and this cannot be in view of the definition of what an ISS in the claim can and cannot be. This is again not persuasive, it is noted that "immunostimulatory" is discussed in the specification to encompass measureable immune response such as antigen-specific antibody production, secretion of cytokines, activation or expansion of lymphocyte populations such as NK,

CD4+, CD8+ T lymphocytes, B lymphocutes and preferably preferentially activate a Th1-response (page 11 of specification). Applicants have not demonstrated that the genus or any species claimed provides for the breadth of immunostimulatory as claimed. The particularities of the measurable response induced by the particular genus is not set forth in the claims. The immune deviation of Th2 to Th1 response is not set forth in the claims as the claims encompass both. Applicants argue that they have provided multiple publications demonstrating the nature of the invention. The examiner has also provided evidence that the mechanisms of CpG' are not understood and that incorporation and positioning of chemical modification are highly unpredicaable. The examiner provided evidence that the length of the oligonucleotide impact ability to immune stimulate and cross-linked microspherses of CpG ODN do not stimulate the immune system. Therefore, the examiner has considered the full state of the art at the time that the invention was made. The unpredictability of the field with respect to length, modifications and type of immune response has been established on this record. The direction of by the inventors has been particularly discussed in the office action mailed 8-1-05 and not reiterated herein. In contrast to Applicants assertions, he presence or absence of working examples is a factor to be considered in highly unpredictable arts and in combination with the established unpredictability of the "ISS" the breadth encompassed by this term, it is clear that Applicants are not enabled for the full scope of the invention. Applicants argue that the quantitation to make and use addition is not undue. This is not persuasive, the experimentation must be routine. In the instant case, the art teaches that changes in structure and length unpredictability affect the properties of the oligonucleotides. Thus, where the exerimentaiton is not predicatble, it cannot be said to be routine. It is maintained that in applications directed to inventions in arts but where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological

activity, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). The working examples are not commensurate in scope with the claims. The examiner has indicated that those are enabled (see scope statement *supra*), however, the claims are not commensurate.

The rejection is maintained.

Claims 1-3, 15-19, 26, 48 stand rejected under 35 U.S.C. 102(e) as being anticipated by Doucette-Stamm et al (US Patent No. 6800744, issued October 5, 2004 with priority to provisional document 60/051,533 filed July 2, 1997) is maintained for reasons made of record in the Office action mailed 8-1-05.

Applicants' arguments have been carefully considered but are not persuasive. Applicants argues Atofina. Atofina is not on point because Doucette-Stamm et al do disclose the complete genus of fragments of single sequence as set forth in the office action mailed 8-1-05 and all are readily envisioned. The claims recite "about" and not merely less than 200. The claims do not have a maximum length of 200 nucleotides as asserted and as such the rejection is maintained.

Status of Claims

Claims 5-8, 27-46 are withdrawn. Claims 1-4, 9-21, 24, 26 and 47-48 stand rejected.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the

application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Th 7:30 pm - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia A. Duffy

Primary Examiner

Art Unit 1645